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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/033,243 | 12/27/2001 | Karen L. Fearon | 377882001800 | 8533 |

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| EXAMINER | |
|---|---|
| DUFFY, PATRICIA ANN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/033,243 | FEARON ET AL. | |
| | Examiner | Art Unit | |
| | Patricia A. Duffy | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The previous restrictions of record are hereby VACATED. The following restriction is set forth based on current linking claim practice within Technology Center 1600.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-21. Claims 2-4, 9-14 drawn to distinct nucleic acids each represented by their individual SEQ ID NO or recited structure, classified in class 514, subclass 44.

Groups 22-37. Claims 6-8, 9-14, drawn to distinct nucleic acids each represented by their individual SEQ ID NO or recited structure, classified in class 514, subclass 44.

Groups 38. Claims 30, 44-46 as drawn to methods of using the distinct nucleic acids of claim 1 for treatment of allergy or asthma classified in class 514, subclass 44.

Group 39. Claims 30, 44-46 as drawn to methods of using the distinct nucleic acids of claim 5 for treatment of allergy or asthma classified in class 514, subclass 44.

Group 40. Claim 42 as drawn to methods of using distinct nucleic acids of claim 1 for mycobacterial infection classified in class 514, subclass 44.

Group 41. Claim 42 as drawn to methods of using distinct nucleic acids of claim 5 for mycobacterial infection classified in class 514, subclass 44.

Group 42. Claim 42 as drawn to methods of using the distinct nucleic acids of claim 1 for treatment of malaria classified in class 514, subclass 44.

Group 43. Claim 42 as drawn to methods of using distinct nucleic acids of claim 5 for treatment of malaria classified in class 514, subclass 44.

Group 44. Claim 42 as drawn to methods of using the distinct nucleic acids of claim 1 for treatment of leishmaniasis classified in class 514, subclass 44.

Group 45. Claim 42 as drawn to methods of using distinct nucleic acids of claim 5 for treatment of leishmaniasis classified in class 514, subclass 44.

Group 46. Claim 42 as drawn to methods of using the distinct nucleic acids of claim 1 for treatment of toxoplasmosis classified in class 514, subclass 44.

Group 47. Claim 42 as drawn to methods of using distinct nucleic acids of claim 5 for treatment of toxoplasmosis classified in class 514, subclass 44.

Group 48. Claim 42 as drawn to methods of using distinct nucleic acids of claim 1 for treatment of schistosomiasis classified in class 514, subclass 44.

Group 49. Claim 42 as drawn to methods of using distinct nucleic acids of claim 5 for treatment of schistosomiasis classified in class 514, subclass 44..

Group 50. Claim 42 as drawn to methods of using distinct nucleic acids of claim 1 for treatment of clonorchiasis classified in class 514, subclass 44.

Group 51. Claim 42 as drawn to methods of using distinct nucleic acids of claim 5 for treatment of clonorchiasis classified in class 514, subclass 44.

Group 52. Claims 34-37 as drawn to methods of using distinct nucleic acids of clam 1 for increasing interferon alpha classified in class 514, subclass 44.

Group 53. Claims 32-33 as drawn to methods of using distinct nucleic acids of claim 5 for increasing interferon gamma classified in class 514, subclass 44.

Group 54. Claims 34-37 as drawn to methods of using distinct nucleic acids of claim 1 for increasing interferon alpha classified in class 514, subclass 44.

Group 55. Claims 32-33 as drawn to methods of using distinct nucleic acids of claim 5 for increasing interferon gamma classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-21 and 22-37 are related but distinct as claimed. The claims represent different polynucleotides that lack a common core structure. As such, the search for one is not co-extensive for the other and would not reveal art on the other and as such would place an undue search and examination burden on the examiner.

Inventions 1-21 are related by a common core structure but distinct as claimed. Each species represents a different chemical structure that would require a different search of the prior art. Because the polynucleotides are chemically distinct in view of

their different structure, the search for one would not anticipate the other and in the absence of restriction would place an undue search and examination burden on the examiner.

Inventions 1-21 and 38, 40, 42, 44, 46, 48, 50, 52, or 54 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used in methods of nucleic acid priming or hybridization.

Inventions 22-37 and 39, 41, 43, 45, 47, 49, 51 or 53 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product could be used in methods of nucleic acid priming or hybridization.

Inventions (38, 40, 42, 44, 46, 48, 50, 52 or 54) and (39, 41, 43, 45, 47, 49, 51, 53 or 55) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in the instant case the methods of invention have different

goals as evidenced by their different preambles, utilize different chemical reagents that lack a common core structure and have different final outcomes (i.e. increasing gamma interferon, increasing alpha interferon or treatment of disease). As such, the groups of methods are independent and distinct as claimed.

Inventions (38, 40, 42, 44, 46, 48, 50, 52 and 54) are related as methods but are distinct as claimed. The methods are distinct as claimed because they have different goals, define exclusive parameters, different final outcomes and treat different populations of patients. The search and examination of the distinct populations of patients is not co-extensive. The search for one patient population would not reveal art on the other divergent patient populations.

Inventions (39, 41, 43, 45, 47, 49, 51, 53 or 55) are related as methods but are distinct as claimed. The methods are distinct as claimed because they have different goals, define exclusive parameters, have different final outcomes and treat different populations of patients.

Claims 1, 15-26, 47 and 48 link(s) inventions 1-21. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 15-26, 47 and 48. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 5, 15-25, 27, 47 and 48 link(s) inventions 22-37. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 5, 15-25, 27, 47 and 48. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 28, 29, 30, 31, 40, 41, 43, link(s) inventions 38-51. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 28, 40 and 43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the lack of co-extensive searches based on results affected variables, populations treated and different chemical structures, because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

If applicants elect any of the recited methods of the inventions as set forth *supra* as groups 38-55 it is noted that :

This application contains method claims directed to the following patentably distinct species of the claimed invention: any single identified nucleic acid sequence disclosed in the specification or specifically claimed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, method claims 28-46 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior

art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or

more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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